GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:543
ANSWERED ON:21.11.2001
NEW PROVISION FOR DRUGS
SUDARSANA E.M. NATCHIAPPAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government have any proposal about the new provision in the drugs and cosmetic rules for the registration of the manufacturing premises of foreign drug manufacturers; and

(b) if so, the details thereof?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR)

(a) & (b): Ministry of Health and Family Welfare vide Gazette of India Notification No. GSR604(E) dated 24.08.2001 have made a new provision in the Drugs and Cosmetics Rules for the registration of manufacturing premises of foreign drug manufacturers.This will come into effect from 01.01.2003.

The application for issue of a Registration Certificate for a manufacturing premise and each manufactured drug by a foreign drug manufacturer for import in India is to be made as per Rule 24-A alongwith the fee of US $1500 and US$1000 respectively.

Details are available in GSR No.604(E) dated 24.08.2001 which is a published document.